Office for Human Research Protections (OHRP), Guidance on IRB Continuing Review of Research, Nov 10, 2010

Expedited Review Category (8)

Under category (8), an expedited review procedure may be used for the continuing review of research previously approved by the IRB at a convened meeting as follows:

(a) Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; **OR**
(b) Where no subjects have been enrolled and no additional risks have been identified; **OR**
(c) Where the remaining research activities are limited to data analysis.

For a multicenter research project, an expedited review procedure may be used by the IRB for a particular institution whenever the conditions of category (8)(a), (b), or (c) are satisfied for that institution. As a result, for some institutions involved in the conduct of a multicenter research project, the IRBs reviewing the project may need to conduct continuing review of the project at a convened meeting, whereas for other institutions, the IRBs may conduct continuing review using an expedited review procedure under category (8).

Expedited review category (8)(a) and the meaning of "long-term follow-up" **(The 2012 FDA Guidance is identical)**

Under expedited review category (8)(a), OHRP interprets "long-term follow-up" to include:

- Research *interactions* that involve no more than minimal risk to subjects (e.g., quality of life surveys); and
- Collection of follow-up data from procedures or interventions that would have been done as part of routine clinical practice to monitor a subject for disease progression or recurrence, regardless of whether the procedures or interventions are described in the research protocol.

In contrast, OHRP interprets "long-term follow-up" to exclude:

- Research *interventions* that would not have been performed for clinical purposes, even if the research interventions involve no more than minimal risk.

However, some research studies that are not eligible for expedited review under category (8)(a) at the time of continuing review may be eligible for expedited review under one of the other expedited review categories. For example, if a research project's only remaining activity involves long-term follow-up of subjects by drawing 15 ml of blood once annually for a test that is not part of routine clinical practice, such research would not be eligible for expedited review under category (8)(a), but might be eligible for expedited review under category (2).

Expedited review category (8)(b)

With respect to category (8)(b), while the criterion that "no subjects have been enrolled" is interpreted by OHRP to mean that no subjects have ever been enrolled at a particular institution, the criterion that "no additional risks have been identified" is interpreted to mean that neither the investigator nor the IRB at a particular institution has identified any additional risks from any institution engaged in the research project or from any other relevant source since the IRB's most recent prior review.

> **The 2012 FDA Guidance:** IRBs conducting continuing review should be aware that if a study previously received expedited continuing review under category (8)(b), but has now begun enrolling subjects, the study may need to be referred for review by the IRB at a convened meeting. The criterion that "no additional risks have been identified" is interpreted by FDA to mean that neither the investigator nor the IRB has identified any additional risks in the research from any relevant source since the IRB's most recent prior review.

Expedited review category (8)(c) and data analysis

OHRP considers a research study to continue to involve *human subjects* as long as the investigators conducting the research continue to obtain: (1) data about the subjects of the research through intervention or interaction with them; or (2) identifiable private information about the subjects of the research (45 CFR 46.102(f)). OHRP interprets *obtaining identifiable private information* to include an investigator's use, study, or analysis of identifiable private information. Therefore, as long as a non-exempt human subjects research study continues to involve use, study, or analysis of identifiable private information by the investigators, the research continues to involve human subjects and must undergo continuing review by an IRB at least annually (45 CFR 46.109(e)), even if the participation of all subjects in a research project has been completed or discontinued. OHRP notes that simply maintaining individually identifiable private information without using, studying, or analyzing such information is not human subjects research and thus does not require continuing review.

Under expedited review category 8(c), an IRB may use an expedited review procedure to conduct continuing review when the only remaining human subjects research activity is the analysis of data that includes identifiable private information and the IRB chairperson (or another experienced IRB member designated by the chairperson) determines that this activity involves no more than minimal risk. OHRP expects that in nearly all cases such research activities will involve no more than minimal risk and therefore be eligible for IRB review under an expedited review procedure.